

The signaling effects of FDA drug designations

Author: Miller, Kathleen L.

ISBN

9781321436334

Abstract

Investors in pharmaceutical firms face substantial information asymmetries. Only a small fraction of drugs that enter development are ever approved by the U.S. Food and Drug Administration (FDA), causing uncertainty for investors. While investors desire information regarding a drug's potential likelihood of a successful approval, firms are limited in their ability to share any proprietary information, because in doing so they may lose their competitive advantage. Instead, firms may use signals to indicate to investors the likelihood of success of drugs in their pipeline.

One such signal is FDA drug designations. Firms apply for the designations from the FDA, and receive them if their drug meets certain federally mandated criteria. The firms can then publicly announce the receipt of a designation to their investors, thereby reducing information asymmetries about a drug's potential market success. Using an event-study methodology utilizing the market model, this dissertation examines three questions regarding the signaling effects of the fast-track designation, the Orphan designation, and stacked designations. In the event study methodology, the strength of a signal is measured by the change in the stock price of a firm after an announcement. This change, aggregated across all events, is known as the cumulative abnormal returns (CARs).

In the first chapter, this dissertation examines whether the fast-track designation acted as a signal to investors (between 1998 and 2012 with $n=196$ firms), and finds CARs of 6.53% after the announcement of a fast-track designation. In the second chapter, this dissertation examines whether the Orphan designation acted as a signal to investors (between 1985 and 2012 with $n=246$ firms), and finds CARs of 3.66% after the announcement of an Orphan designation. In the third chapter, this dissertation analyzes whether the announcement of a stacked designation (a fast-track designation with a prior Orphan designation) produce higher CARs than non-stacked fast-track destinations (between 1998 and 2012 with $n=30$ stacked designations and $n=166$ non-stacked designations). The analysis finds CARs of 7.47% for the stacked designations, and CARs of 6.63% for non-stacked designations. Each chapter also analyses longitudinal differences in CARs, as well as differences in CARs based on firm size.

Advisor

[Reiter, Kristin](#)

University/institution

The University of North Carolina at Chapel Hill

Department

Health Policy and Management

University location

United States -- North Carolina

Degree

Ph.D.

Source type

Dissertations & Theses

Language

English

Document type

Dissertation/Thesis

Dissertation/thesis number

3668522

ProQuest document ID

1648168700

Document URL

<http://libproxy.lib.unc.edu/login?url=https://search.proquest.com/docview/1648168700?accountid=14244>